

**ELECTION**

Applicants provisionally elect with traverse, Group I as outlined in the office action mailed December 29, 2009, containing Claims 73-116 for further examination in the present application.

### **REMARKS**

Applicants thank the Examiner for consideration of the subject patent application. In the office action mailed December 29, 2009, Claims 73-145 were pending, and made subject to a restriction requirement under 35 U.S.C. § 121. Particularly, the Examiner indicated that Claims 73-116 were drawn to a pharmaceutical composition (Group I), Claims 117-118 were drawn to a method for the preparation of a pharmaceutical composition (Group II), and Claims 119-145 were drawn to a method of treating a subject suffering from prostate disease (Group III). Therefore, if the present provisional election is made final, Claims 73-116 will remain for consideration in the present patent application, and Claims 117-145 will be withdrawn from consideration.

Applicants respectfully traverse the present restriction requirement. Specifically, the Examiner alleges that restriction of the present claims is proper, citing PCT Rules 13.1 and 13.2 as the basis there for, and alleging that there is no common or shared special technical feature in view of U.S. 2003170307. Applicants respectfully disagree. A review of the corresponding PCT application file history reveals that though subject to these same PCT Rules 13.1 and 13.2, no lack of unity was ever found during the entire PCT proceeding. Moreover, Applicants respectfully disagree with the Examiner's assessment of the present claims as lacking a common special technical feature in view of U.S. 2003170307. Particularly, reference to the international phase of the corresponding PCT application clearly reveals that the relevant independent claims were deemed to be novel over U.S. 2003170307 and the other references presented in the International Search Report (ISR).

Moreover, the presently pending independent claims were amended at the time of entry into the U.S. national phase to include recitation of specific pharmaceutically active agents. Such

recitation further distances the claims from the teachings contained in U.S. 2003170307. Furthermore, there are additional differences in the disclosure and teachings of the U.S. 2003170307 reference which set it apart from the present claims. Foremost is the fact that U.S. 2003170307 teaches compositions utilizing matrix polymers and/or complexing agents as the mechanism for controlling active agent release. Specific matrix polymers are selected and used to control the erosion rate of the composition, thereby altering viscosity in the pores and channels of the formulation and impacting the release profile of the active agent. Complexing agents are used to form conjugates with the active agent and further slow release rate and flux.

By contrast, the invention of the present claims requires that the formulation have a ruptured structure when the formulation is in solid form. Such a formulation has a large apparent surface area that is exposed to degradation when administered to a subject. Nothing in U.S. 2003170307 teaches or suggests any such structure or mechanism.

In view of the foregoing, Applicants submit that restriction of the claims by the Examiner is improper and respectfully request that the restriction requirement be withdrawn.

**CONCLUSION**

If any impediment remains to examination after consideration of the above-recited remarks, which could be removed during a telephone interview, the Examiner is invited to telephone Mr. David Osborne of this office, or in his absence, the undersigned attorney at (801) 566-6633 so that such issues may be resolved as expeditiously as possible.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 20-0100.

DATED this 7<sup>th</sup> day of April, 2010.

Respectfully submitted,

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